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HEALTHsense®

USER MANUAL

Heart-Mate Digital Blood Pressure Monitor

Model : BP 100

Classic



Sensing **Health** Everywhere

- Thank you very much for purchasing HealthSense Heart -Mate Digital Blood Pressure Monitor BP 100 Classic.
- Please READ this manual thoroughly and carefully to ensure safe usage of this product. Retain the manual for future references.

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♥ General Description

Thank you for selecting HEALTHSENSE arm type blood pressure Monitor (BP-100 Classic). The monitor features blood pressure measurement, pulse rate measurement, talking function and the result storage. The design provides you with one year of reliable service.

Readings taken by the BP-100 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method. This manual contains important safety and care information, and provides step by step instructions for using the product. Read the manual thoroughly before using the product.










♥ Indications for Use

The HealthSense Blood Pressure Monitor is digital monitor intended for use in measuring blood pressure and heartbeats rate with arm circumference ranging from 22 cm to 42 cm (about 8¾"-16½").

It is intended for adult indoor use only.

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS"
	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"		Symbol for "ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice"
	Symbol for "SERIAL NUMBER"		
	Symbol for "DIRECT CURRENT"		Caution: These notes must be observed to prevent any damage to the device.
	Symbol for "MANUFACTURE DATE"		

CAUTION

The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.

The device is not suitable for use on pregnant women, patients with implanted, electrical devices, patients with pre-ecampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy. Please consult your doctor prior to using the unit if you suffer from illnesses

Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.

Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.

⚠ CAUTION

This device is intended only for adult use in homes.

This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than arm or for functions other than obtaining a blood pressure measurement.

If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.

On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure >300mmHg or constant pressure >15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.

Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.

Do not wrap the cuff on the same arm which other monitoring ME EQUIPMENT is applied simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT.

Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.

The maximum temperature that the applied part can be achieved is 42.5°C while the environmental temperature is 40°C. (only for wrist blood pressure monitor)

The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

This unit is not suitable for continuous monitoring during medical emergencies or operations.

This device cannot be used with HF surgical equipment at the same time.

This device is not intended for patient transports outside a healthcare facility.

To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.

The operator shall not touch output of batteries/adaptor and the patient simultaneously.

Manufacturer will make available on request circuit diagrams, component parts list etc.

The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensitization or irritation reaction. Never apply the cuff over hurt skin.

Do not use the unit in case of existing polyester resp. synthetic allergies.

Be careful of strangulation due to cables and hoses, particularly due to excessive length.

Do not connect the air hose to other medical equipment, as this could cause air to be pumped into intravascular systems or high pressure, what could lead to dangerous injuries.

Before use, make sure the device functions safely and is in proper working condition.

Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.

Please use ACCESSORIES and detachable parts specified/ authorised by MANUFACTURER.

Otherwise, it may cause damage to the unit or danger to the user/patients.

Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

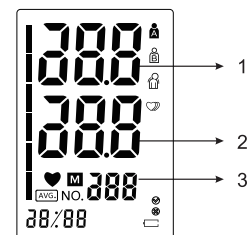
Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorized service centers.

Please report to Manufacturer if any unexpected operation or events occur.

The device doesn't need to be calibrated in two years of reliable service.

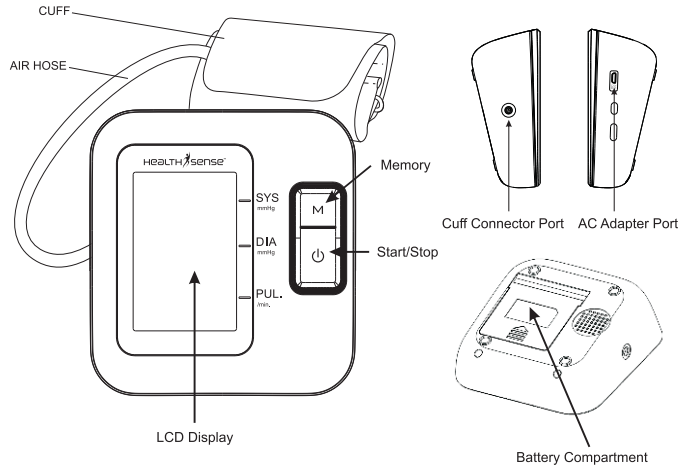
Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

♥ LCD display signal



	SYMBOL	DESCRIPTION	EXPLANATION
1	200	Systolic blood pressure	High pressure result
2	80	Diastolic blood pressure	Low pressure result
3	88	Pulse per minute	Beats per minute, BPM
	I	WHO Symbol	Shows BP level as per WHO standards
	M NO.	Memory	The displayed measurement values are from the memory.
	Low battery icon	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat icon	Irregular heartbeat	Irregular heartbeat Detection
	28:88	Current Time	Year/Month/Day, Hour/Minute
	Heartbeat icon	Heartbeat	Heartbeat detection during the measurement
	User A icon	User A	Start measurement and save the measuring results for User A
	User B icon	User B	Start measurement and save the measuring results for User B
	AVG	Average Value Symbol	Average reading will be displayed
	Body Movement Indicator icon	Body Movement Indicator	Detects body movement
	Cuff self-checking function icon	Cuff self-checking function.	The device will check if your cuff tying is correct or not.

♥ Monitor Components



IN THE BOX

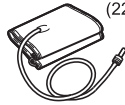
1. Blood Pressure Monitor
(Heart-Mate BP 100 Classic)



3. 4×AAA batteries



2. Cuff (Type BF applied part)
(22cm~42cm)



(Please use HEALTHSENSE authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)

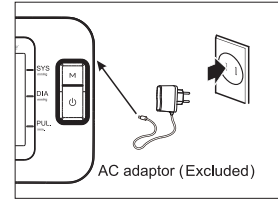
4. User manual

5. Warranty Card

♥ The Choice of Power Supply

1. Battery powered mode:
6VDC 4×AAA batteries
2. AC adaptor powered mode:
5V $\overline{\text{---}}$ 1A (Micro USB Port 'C' Type)
(Please only use the recommended AC adaptor model).

Ensure to remove batteries from the compartment before using AC Adaptor

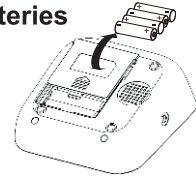


⚠ CAUTION


In order to get the best effect and protect your monitor, please use the right battery and special power adaptor which complies with CE safety standard.

♥ Installing and Replacing the Batteries

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the cover.



Replace the batteries whenever the below happen

- The  shows
- The display dims
- The display does not light up

⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.


♥ Measurement Principle

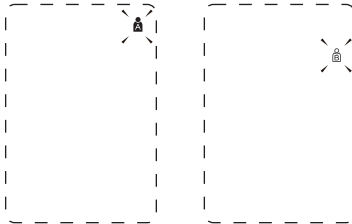
This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.


The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.


♥ Setting User, Date, Time


It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year : 2019-2049 time format: 24H)

1. When the monitor is off, press "  " button about 3 seconds to enter user setting mode. The user will display.

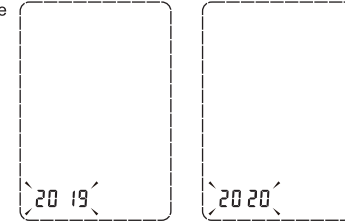


2. Press "  " button to select the user ID between user A and user B.

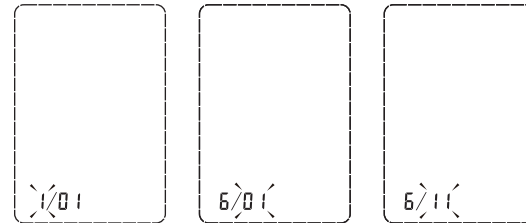
3. After selecting the suitable user ID, press "  " button to confirm & enter Year settings.

4. Press "  " button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.

Note: There is no descending order while selection. Continue pressing 'M' button until the desired selection is reached.



5. When you set the right year, press "  " button to set down and turn to next step. Now you can set the [DATE] M/D.

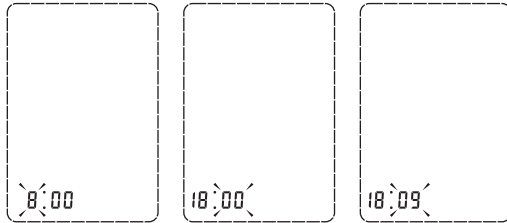


6. Repeat steps 4 and 5 to set the [MONTH] and [DAY].

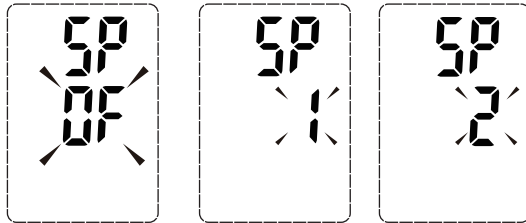
BEFORE YOU START

7. Repeat steps 4 and 5 to set the [HOUR] and [MINUTE]. Shown below for 24H format

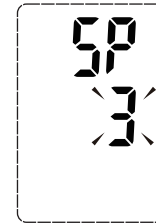
Note: There is no descending order while selection. Continue pressing 'M' button until the desired selection is reached



8. After setting time, press '(O) button to confirm and move to set Speaker Volume. When display flashes SP, press 'M' button to shuffle & select between Volume 1, 2, 3, or OFF. Press '(O) button to confirm



BEFORE YOU START



9. After setting volume, pressing '(O) button will switch off the monitor.



♥ Select the User

1. Press "M" button to select the user ID between user A and user B.



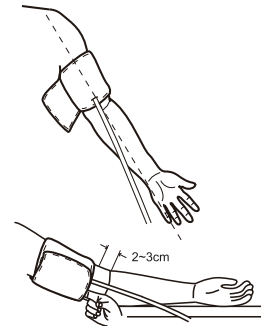
2. After selecting the suitable user ID, keep pressing "O" button to skip all other settings to confirm selected user id, and at last the LCD will turn off.

♥ Cuff Wrapping

1. Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger.

Note: Ensure to select User A or B before taking a measurement

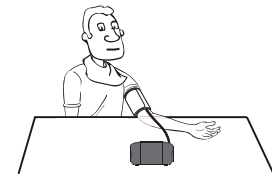
2. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



3. Sit comfortably with your tested arm resting on a flat surface.

4. Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart;
Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.

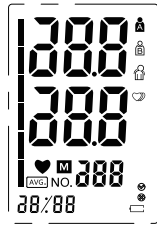


- After wrapping the cuff, connect the loose end of the air hose pipe to the cuff connector port.

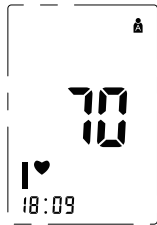
♥ Start the Measurement

- When the monitor is off, press the "⊙" button to turn on the monitor, and it will finish the whole measurement.
(Take user A for example.)

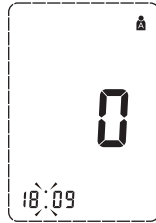
LCD display



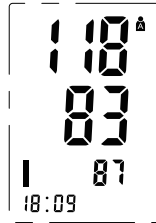
Inflating and measuring.



Adjust to zero.



Display and save the measurement results.



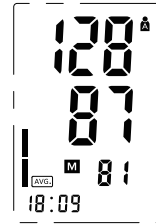
- Press the "⊙" button to power off, otherwise it will turn off within 1 minute.

Tips: Maximum 90 records each for User A & User B

♥ Recall the Records

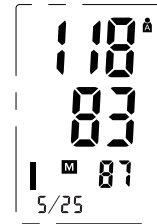
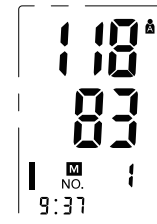
- When the monitor is off, press "M" button to show the average value of the latest three records.

(Note: If the records are less than 3 groups, the LCD will still display average record of the last saved memory)

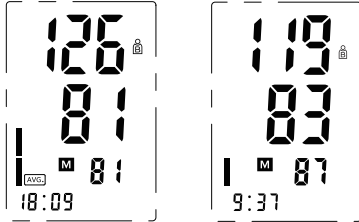


- Press "M" button to get the record for your other stored memory (from M no.1 to M no. 90)

(Note: The order, date and time of the record will be shown alternately)



3. If you want to check another user records, press "⊙" button to turn off the monitor. Now follow steps 1, 2 & 3 as per page 12 to select the user ID between user A and user B. After selecting user B repeat steps 1 & 2 as per page 15 to read average & memory readings for user B.



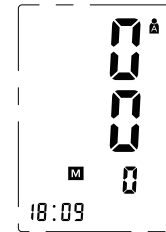
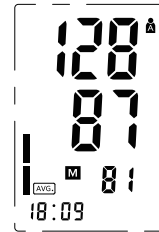
⚠ CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (120) is dropped from the list.

♥ Delete the Records

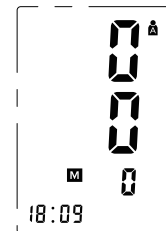
If you did not get the correct measurement, you can delete all results by following steps below. (Take User A for example.)

1. Press "M" button to enter memory mode. The flash display will show average saved memory
2. Press and hold "M" button to confirm deleting and the monitor will display as below



Note: To exit out of delete mode without deleting any records, press "⊙" button before pressing "M" to confirm any delete commands.

3. If there is no record. The following display will show.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



Within 1 hour
after dinner or drinking



Immediate measurement
after tea, coffee, smoking



Within 20 minutes
after taking a bath



When talking or moving your fingers



In a very cold environment

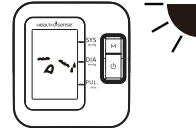


When you want to discharge urine



♥ Maintenance

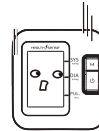
In order to get the best performance, please follow the instructions below



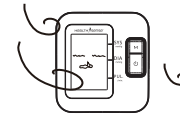
Put in a dry place and avoid the sunshine



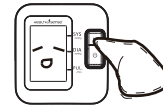
Avoid touching water,
clean it with a dry cloth in case.



Avoid intense shaking
and collisions



Avoid dusty and unstable
temperature environment



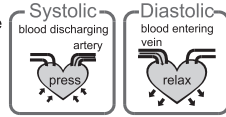
Using wet cloths to remove dirt



Do not attempt to clean the reusable cuff
with water and never immerse the cuff in
water.

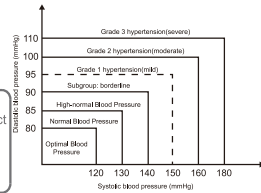
♥ **What are systolic pressure and diastolic pressure?**

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ **What is the standard blood pressure classification?**

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



⚠ CAUTION
Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Blood Pressure (mm Hg)	Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS		<120	120-129	130-139	140-159	160-179	≥180
DIA		<80	80-84	85-89	90-99	100-109	≥110

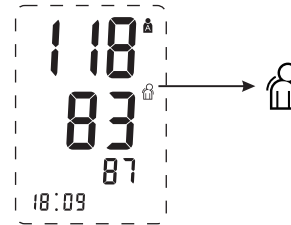
♥ **Irregular Heartbeat Detector**

An irregular heartbeat is detected (⊡) when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.

⚠ CAUTION
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ **Body movement Indicator**

If you move during measurement, the movement error symbol (⊠) will appear on the display. Keep still and repeat the measurement



♥ **Why does my blood pressure fluctuate throughout the day?**

1. Individual blood pressure varies multiple time everyday depending on food intake and various activities, including your emotions. It is also affected by the way the cuff is tied and your seating/sleeping position.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.



♥ Why do I get a different blood pressure at home compared to the hospital ?

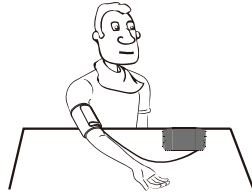
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the "white coat" effect, which means blood pressure usually increases in clinical settings.

♥ Is the result the same if measuring on the right arm ?

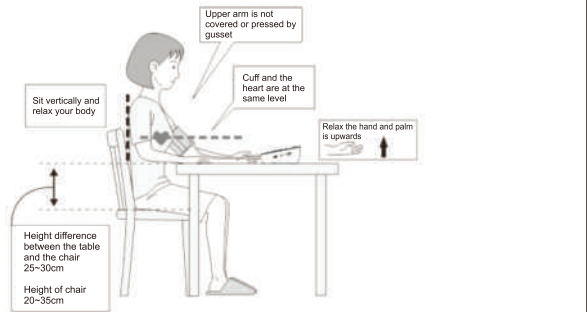
It is ok for both arms, but there will be some different results for different people. We suggest you to measure on same arm every time.

What you need to pay attention to when you measure your blood pressure at home:

- If the cuff is tied properly.
- If the cuff is too tight or too loose.
- If the cuff is tied on the upper arm.
- If you feel anxious.
- Taking 2-3 deep breaths before beginning will be better for measuring.
- Advice: Relax yourself for 4-5 minutes until you calm down.



♥ How to Sit Correctly ?



This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

SYMBOL	CAUSE	CORRECTION
No display appears	Weak battery or improper placement	Replace both batteries with new ones. Check the battery installation for proper placement of the battery polarities.
Er1	Sensor abnormal	Send it to the local distributor
Er2	Monitor could not detect pulse wave	Make sure the air plug is properly inserted in the unit
Er3	Measurement result is abnormal (SYS<45mmHg or DIA<24mmHg)	Occasionally - measure for one more time/Always - Send it to local distributor.
Er4	It appears during the process of inflating	Wrap the cuff properly
Er5	Pipe blocked	Make sure the air flow smooth.
Er6	Heart rate area display "Hi"	Heart rate is more than 200 beats/Min.
Er7	Heart rate area display "Lo"	Heart rate is less than 40 beats/Min.
Err 21	Internal board issue	Contact HealthSense Customer Support Team

PROBLEM	CHECK THIS	REMEDY
No Power	Check the battery power. Check the battery polarity position	Replace with new sets of batteries. Proper installation of batteries polarities
No inflation	Check the air hose plug	Tightly insert plug in air socket
Err and stop working	Movement of arm or body while measurement Talking while measurement	Keep the body peaceful Keep quiet when measuring
Cuff leak	Whether the cuff wrap is too loose. Whether the cuff is broken	Wrap the cuff tightly Change to new cuff
<p>⚠ Please contact HealthSense Customer care if you can't solve the problem, do not disassemble the unit or perform unauthorized repair by yourself</p>		

SPECIFICATIONS

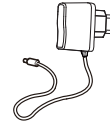
Power supply	Battery powered mode: 6VDC 4×AAA batteries AC adaptor powered mode: 5V $\overline{\text{DC}}$ 1A (Please only use the recommended AC adaptor model). (excluded)
Display mode	Digital LCD V.A. 40 x 60 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~300mmHg pulse value: (40-199) beat/minute
Accuracy	Pressure: 5°C-40°C within \pm 3mmHg pulse value: \pm 5%
Normal working condition	Temperature:5°C to 40°C Relative humidity: \leq 85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20°C-60°C Relative Humidity: \leq 93%RH Atmospheric Pressure: 50kPa-106 kPa
Measurement perimeter of the upper arm	About 22cm~42cm
Net Weight	Approx. 225g (excluding the dry cells and cuff)
External dimensions	N.W. 207g, G.W. 485g
In the box	Classic BP-100, 4×AAA batteries, BP Cuff, User manual & Warranty card
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	V01

WARNING: No modification of this equipment is allowed.

AUTHORIZED COMPONENTS

♥ Authorized Components

1. Please use AC Adapter with below power specifications only (Adaptor not included in package)
2. Please use HEALTHSENSE BP series cuff (22-42 cm)



Adapter
Input: 100-240V~, 50/60Hz,0.4A Max
Output: 5V $\overline{\text{DC}}$ 1A



WARRANTY & SUPPORT

Entitle yourself for the 1 year HealthSense warranty by registering your purchase and easily reach us to submit your product related issues & queries, when you follow these hassle free ways.

At HealthSense our top priority has always been our valued customers. We very well know your HealthSense product is a part and parcel of your everyday life, which is why we are more easily accessible than earlier.

SCAN - For Warranty Registration



(Must register within 30 days from date of purchase)

SCAN - To File Complaint



(Fill & submit form if you are facing any product related issues)

* For detailed warranty terms please visit the link :

www.healthsense.in/warranty-terms

* For additional support :

Mail us at : support@healthsense.in or Call us on : 080-41262836

♥ Complied European Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	EN 980 Symbols for use in the labelling of medical devices
User manual	EN 1041:2008 Medical equipment manufacturers to provide information
General Requirements for Safety	EN 60601-1: 2006+A1:2013 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC/EN 60601-1-11: 2010 Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements	EN ISO 81060-1:2012(new) Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007) EN 1060-3:1997+A2:2009 Non-invasive blood pressure Part 3: Supplementary requirements for electromechanical blood pressure measuring system
Clinical investigation	EN 1060-4: 2004 Automatic Blood Pressure Monitor overall system Interventional accuracy of the testing process
Usability	IEC/EN 60601-1-6: 2010 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability IEC/EN 62366: 2007 Medical devices - Application of usability engineering to medical devices
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes

♥ EMC Guidance

1) This equipment needs to be installed and put into service in accordance with the information provided in the user manual;

2) Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance $d=3,3m$ away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d=3, 3m$ at an IMMUNITY LEVEL of 3V/m)